NO. 17-1229

IN THE

Supreme Court of the United States

HELSINN HEALTHCARE S.A.,
Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC., ET AL.,
Respondent.

On Writ of *Certiorari* to the United States Court of Appeals for the Federal Circuit

BRIEF OF *AMICUS CURIAE* IEEE-USA IN SUPPORT OF AFFIRMANCE

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INTEREST OF *AMICUS CURIAE* [1]

IEEE-USA is an organizational unit of The Institute of Electrical and Electronics Engineers, Inc. (IEEE), the world's largest technical professional organization dedicated to advancing technology for the benefit of humanity. IEEE-USA supports the nation's prosperity and competiveness by fostering technological innovation for the benefit of all, including nearly 200,000 U.S. engineers, scientists, and allied professionals who are members of the IEEE.

As part of its mission, IEEE-USA seeks to ensure that U.S. intellectual property law "promote[s] the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. Art. I, § 8. IEEE-USA's members have a substantial stake in the U.S. patent system. Our membership includes inventors who create and use cutting-edge technology, researchers who are involved in scientific discovery, authors of

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[1] Pursuant to Supreme Court Rule 37.6, counsel for the *amicus curiae* certifies that no counsel for any party authored this brief in whole or in part and that no person or entity other than the *amicus*, its membership, or its counsel made a monetary contribution intended to fund the preparation or submission of the brief. The parties have filed blanket consents to the filing of *amicus* briefs and their letters are filed with the clerk.

journal articles in the broad fields of engineering and science, entrepreneurs, and employees of firms that acquire, license, and market patented technology. IEEE-USA has consistently advocated for the full legislative restoration of the pre-AIA American grace period, which neither parties' statutory construction of the AIA achieves.[2] While IEEE-USA supports Respondent on the statutory construction question presented, we take no position on the ultimate question of the validity or infringement of the patents at issue in this case.

SUMMARY OF ARGUMENT

Does U.S. patent law under the America Invents Act of 2011 ("AIA") permit the issuance of patents to inventors after they have had an unlimited exclusive period of secret commercialization of the invention? *Amicus* IEEE-USA argues that the answer is 'No' – the same answer as that held by the courts before enactment of the AIA. Under the same principles, this brief also argues that the AIA did not change the "experimental use" doctrine that protects inventors during their pre-filing activities for testing and perfecting their inventions.

For more than two centuries, American patent law provided that an inventor forfeits the right to a patent for his invention that had been "on sale" or in

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[2] *See* IEEE-USA, *Patent Prior Art and Grace Period, Position Statement*, (November 18, 2016), available http://ieeeusa.org/wp-content/uploads/2017/02/PriorArt1116.pdf

"public use" longer than a set grace period before the filing date of his patent application. That is so even if such sale or use did not disclose to the public the invention. Petitioner Helsinn argues that the change in the statute under the AIA must be read as having repealed this forfeiture bar – that as long as the invention is not disclosed to the public, secret commercialization of an invention does not bar patenting it any time later. Examples of inventions in this secret commercial use category are methods of manufacture, process of making, or composition of matter, which cannot be learned from the end product used by, or sold to, the public.

The Federal Circuit correctly held otherwise and rejected the argument that the AIA repealed the secret commercialization forfeiture bar. This Brief urges affirmance of that decision. The Brief marshals evidence and a constitutional avoidance doctrine to show that Congress neither intended to change, nor changed, the meaning of the statutory terms "on sale" and "public use" in the AIA statute.

The Brief shows that under the Petitioner's alternative construction, there would be substantial disruption to innovation because the statute may plausibly be interpreted as foreclosing on the "experimental use" exception to "on sale" and "public use," causing massive loss of patent rights.

ARGUMENT

This case presents an important question: did the meaning of the statutory terms of art "on sale" and "public use" in the patent law change under the America Invents Act, PL 112-29, 125 Stat. 284 (2011) ("AIA")? *Amicus curiae* IEEE-USA shows below that the answer is decidedly "No." The Federal Circuit correctly held that "the AIA did not change the statutory meaning of 'on sale' in the circumstances involved here." *Helsinn Healthcare v. Teva Pharmaceuticals*, 855 F.3d 1356, 1360 (Fed. Cir. 2017).

Although the Question Presented in this case is limited to the statutory meaning of "on sale" in post-AIA § 102(a)(1), the immediately-preceding term in the text, "public use," is subject to identical statutory construction principles due to its location in the sentence and due to its having been invoked as a counterpart to the "on sale" personal bar against the inventor under identical patent policy principles. Because it is imperative that any ambiguities in the post-AIA statute of Section 102(a)(1) be resolved with finality, this Court's decision should address both terms. For this reason, this brief addresses both the "on sale" and the "public use" bars as counterparts.

I. THE TERMS "ON SALE" AND "PUBLIC USE" ARE INGRAINED IN THE FABRIC OF THE AMERICAN INNOVATION PRACTICE

Over nearly two centuries of American jurisprudence, the statutory terms "public use" and "on sale" in patent law have received specific and well-established meanings. Those were laid out in precedential case law spanning more than 640 federal cases identified in the American Law Reports. William G. Phelps, "When does on–sale bar of § 102(b) [ ] prevent issuance of valid patent," 155 *A.L.R. Fed.* 1 (2010); Kurtis A. Kemper, "When is Public Use [ ] for Experimental Purposes, so that § 102(b) Does Not Prevent Issuance of Valid Patent," 171 *A.L.R. Fed.* 39 (2010). These statutory terms, their interpretation, and recognized related exceptions govern the established practices and conduct of technology developers in perfecting, commercializing, testing, disclosing, promoting, and marketing their inventions. Over decades, American industries have built procedures for inter-company contracting, disclosure, collaboration, and structuring business transactions based on the settled interpretation of these statutory terms.

Under pre-AIA law, a definite sale or an offer for sale of the invention prior to the critical date need not itself disclose the claimed invention to make the patent invalid under the "on–sale" bar. *Pennock v. Dialogue*, 27 U.S. 1, 19 (1829) (Invalidating a patent when inventor commercially exploited the invention and withheld from "the public the secrets of [the] invention."); *RCA Corp. v. Data General Corp.*, 887

F.2d 1056, 1060 (Fed.Cir.1989), *different part overruled* by *Group One v. Hallmark*, 254 F.3d 1041 (Fed.Cir.2001). Where an inventive method is kept secret, and remains secret after a sale of the product of the method, that sale will not bar another inventor from patenting that method. It will, however, bar a patent if that sale of the product was made before the critical date by the applicant for that patent or its assignee. *D.L. Auld Co. v. Chroma Graphics Corp.*, 714 F.2d 1144 (Fed.Cir.1983). It was not required that members of the public be aware that the product "on sale" actually embodies the claimed invention. *Abbott Laboratories v. Geneva Pharmaceuticals, Inc.*, 182 F.3d 1315, 1317–18 (Fed. Cir. 1999). Indeed, a long line of precedent holds that secret commercialization by the inventor bars patentability. "If an inventor should be permitted to hold back from the knowledge of the public the secrets of his invention," commercially exploit it exclusively and later "take out a patent," that "would materially retard 'the progress of ... the useful arts'" and "give a premium to those ... least prompt to communicate their discoveries." *Pennock*, 27 U.S. at 19 (Story, J.) (quoting U.S. Const. Art. I, §8, cl. 8). Courts have thus adhered to an equitable maxim that "[i]t is a condition upon the inventor's right to a patent that he shall not exploit his discovery competitively after it is ready for patenting; he must content himself with either secrecy or legal monopoly." *Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516, 520 (2nd Cir. 1946) (Learned Hand, J.), *cert. denied*, 328 U.S. 840 (1946); *Bonito Boats v. Thunder Craft Boats*, 489 U.S. 141, 149 (1989) (quoting *Metallizing* with approval); *Pfaff v. Wells Elecs., Inc.*,

525 U.S. 55, 68 (1998) (quoting *Metallizing* with approval).

Similarly, under pre-AIA law, it is unnecessary for an invention to be disclosed while in "use" to be considered "public" so as to bar a patent under pre-AIA 35 U.S.C. § 102(b)—the invention need only be accessible to the public, even if access to the information is practically infeasible. *Hall v. Macneale*, 107 U.S. 90, 96 (1883) (inventor's three "burglar-proof" safes were in public use, despite the invention being completely concealed within safe); *New Railhead Mfg. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1299 (Fed. Cir. 2002) (patent held invalid for public use even though drill bit invention operating underground could not be viewed in operation). "It is not public knowledge of his invention that precludes the inventor from obtaining a patent for it, but a public use or sale of it." *TP Labs., Inc. v. Professional Positioners, Inc.*, 724 F.2d 965, 970 (Fed.Cir.1984). The term 'public' means merely 'not secret.' *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1549 (Fed.Cir.1983) ("The nonsecret use of a claimed process in the usual course of producing articles for commercial purposes is a public use"). Use of an invention is deemed not secret when "used by a person other than the inventor who is under no limitation, restriction, or obligation of secrecy to the inventor." *In re Smith*, 714 F.2d 1127, 1134 (Fed.Cir.1983) (citing *Egbert v. Lippmann*, 104 U.S. 333, 336 (1881)).

For over more than a century, courts have also recognized the equitable doctrine of the "experimental use" exception to the "on sale" and

"public use" bars. It is a settled safe harbor during a limited period for a bona fide experimental purpose of testing or perfecting the invention rather than using it for commercial exploitation. According to the experimental use exception, such invention-disclosing public-use would not bar a patent. *City of Elizabeth v. American Nicholson Pavement Co.*, 97 U.S. 126 (1877) (A patent for an improved pavement held valid even though the segment of the pavement about 75 feet in length on a road by way of experiment was publicly used). Similarly, where a sale is primarily for a bona fide experimental purpose to test or perfect the invention rather than for commercial exploitation, the prior sale does not bar patent validity. *A.B. Chance Co. v. RTE Corp.*, 854 F.2d 1307, 1311 (Fed.Cir.1988). *Envirotech Corp. v. Westech Eng'g Inc.*, 904 F.2d 1571, 1574 (Fed. Cir. 1990).

Generally, the time limit for filing a patent application after its first public use or commercial exploitation is set by a congressional policy grounded in the U.S. Constitution, as suggested in *Pennock*. From the Patent Act of 1790 to the present day, any sale or public use of an article ready for patenting, if not closely followed by filing a patent application, has acted as a *forfeiture* of patent protection for any invention embodied in the article or its manufacture. "[T]he inventor who designedly, and with the view of applying it indefinitely and exclusively for his own profit, withholds his invention from the public comes not within the policy or objects of the Constitution or acts of Congress. He does not promote, and, if aided in his design, would impede, the progress of science

and the useful arts." *Kendall v. Winsor*, 62 U.S. 322, 328 (1858) (citing U.S. Const. art. I, § 8, cl. 8).

Section 102(b) under pre-AIA law "is primarily concerned with the policy that encourages an inventor to enter the patent system *promptly*." *Woodland Tr. v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed. Cir. 1998) (emphasis added). "Thus an inventor's own prior commercial use, albeit kept secret, may constitute a public use or sale under § 102(b), barring him from obtaining a patent." *Id.* This bar is part of the *quid pro quo* of the patent bargain – "it is part of the consideration for a patent that the public shall *as soon as possible begin* to enjoy the disclosure. *Metallizing*, 153 F.2d at 520 (Learned Hand, J.) (emphasis added). Repealing this bar may result in *indefinite* "practical monopoly by means of secrecy and of a later legal monopoly by means of a patent." *Metallizing*, 153 F.2d at 519.

Thus, the "on sale" and "public use" equitable forfeiture bars to patentability are distinct from *prior art* bars. Quite apart from any *disclosure* considerations, "on sale" and "public use" in this context define commercial *conduct* under which the inventor *forfeits* the right to a patent when balancing the equities of the inventor and the public. This balance is *a matter of policy* grounded in our Constitution. For reasons explained below, these sound constitutionally-grounded policies were not repealed by Congress' enactment of the AIA in 2011.

II. CONGRESS DID NOT CHANGE THE MEANING OF "ON-SALE" AND "PUBLIC USE" IN ENACTING THE AIA

Post-AIA 35 U.S.C. § 102(a)(1) bars a patent if "the claimed invention was patented, described in a printed publication, or in public use, on sale, *or otherwise available to the public* before the effective filing date of the claimed invention." (Emphasis added).

The plain language here shows that Congress did not overturn the settled meaning of "on sale" and "public use" by adding the new residual category "or otherwise available to the public." This new term is a disjunctive that captures disclosures through media and modalities that are not in patents, "in a printed publication," or in "public use."

II.A The residual term "otherwise available to the public" covers a growing non-overlapping category of prior art.

Helsinn's interpretation does not merely change the settled meaning of the terms "on sale" and "public use;" its interpretation (at 4) that perverts the "new catch-all provision" as a clarification that "informs the meaning of the language that precedes it" sidesteps the congressional purpose of explicitly providing for the residual prior art category. For example, the IEEE Collabratec® integrated online community platform connects technology professionals all over the world.[3] In 2017 alone, its

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[3] *See* http://ieee-collabratec.ieee.org/

user base grew by 61 percent to include more than 120,000 registered users. [4] This online platform facilitates sharing knowledge and expertise through globally diverse, engineering-focused communities. A technical item shared with other users on the IEEE Collabratec® platform is not literally a "printed publication." And when operating on user device "apps," which are *not* webpages *per se*, such sharing may *not* be necessarily construed as judicially-recognized equivalent of a "printed publication."[5] Clarifying the scope of the prior art to include public disclosure in such new technological modalities is the purpose of the AIA's residual category of "otherwise available to the public;" Congress' purpose was to update the statute to cover emerging public dissemination technologies since the Patent Act of 1952.

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[4] IEEE, *Annual Report 2017*, at 23.

[5] The Federal Circuit has held such equivalence even for unindexed public sources on the internet, *e.g.*, *Voter Verified, Inc. v. Premier Election Solutions, Inc.*, 698 F.3d 1374, 1379–81 (Fed. Cir. 2012) (holding that content on a "website" is "printed publication"); *Suffolk Techs., LLC v. AOL Inc.*, 752 F.3d 1358, 1364–65 (Fed. Cir. 2014) (holding that a Usenet newsgroup posting is "a printed publication.")

II.B The doctrine of constitutional avoidance counsels statutory construction that preserves the settled meaning of "on sale" and "public use"

Apart from fundamental conflicts with statutory construction principles discussed in the briefs of the Respondent and its other *amici*, Helsinn's construction of Post-AIA § 102(a)(1) raises serious constitutional questions. This is because such construction repeals the forfeiture bars to patenting, which may exceed the Constitutional "limited times" notion and the "progress" limits on Congress' authority. As Justice Story explained in *Pennock*, allowing the inventor "for a long period of years" to "retain the monopoly and make and sell the invention publicly, and thus gather the whole profits of it," and thereafter allowing him "to take out a patent, and thus exclude the public from any further use than what should be derived under it during" the patent term, "would materially retard the progress of science and the useful arts and give a premium to those who should be least prompt to communicate their discoveries." *Pennock*, 27 U.S. at 19 (Story, J.) (quoting U.S. Const. Art. I, §8, cl. 8). Thus, by allowing the inventor to delay without bound the disclosure of the invention, Congress would "not promote," but "would impede, the progress of science and the useful arts." *Kendall* 62 U.S. at 328 (citing U.S. Const. art. I, § 8, cl. 8). *See* Ron D. Katznelson, "The America Invents Act May Be Constitutionally Infirm if It Repeals the Bar Against Patenting After Secret Commercial Use," 13 *Engage: J. Federal Society Practice Groups*, 73, 74-76 (October 2012); D.H. Crawley, "America Invents Act: Promoting

Progress or Spurring Secrecy?," 36 *U. Haw. L. Rev.* 1, 24-25 (2014) (allowing "patenting even after years of secret commercialization" would violate "the constitutional mandate"; "Without the public disclosure of patenting, other inventors cannot build on the invention to advance technology, and the progress of science and the useful arts is retarded, not promoted.")

The U.S. Constitution cabins Congress' power, restricting it to "securing for *limited times* to authors and inventors the *exclusive right.*" That restriction on Congressional power is not confined merely to securing exclusive rights in issued patents – it also encompasses any de-facto pre-issuance exclusivity that Congress may indirectly "secure" by incentives created by its statutory scheme that controls inventors' rights and obligations prior to filing. Helsinn's construction of post-AIA § 102(a)(1), however, would do just that. It would hold that Congress authorized inventors to receive a patent after an *indefinite* period of secret *exclusive* exploitation of their invention, and therefore necessarily *secured* the *exclusive* period for an *indefinite* duration at the *inventors'* discretion. *Metallizing*, 153 F.2d at 520 (Learned Hand, J.) (by "making use of his secret to gain a competitive advantage over others," the inventor would "thereby extend the period of his monopoly"); *See* Katznelson, *Supra.* at 76. This de facto indefinite extension of exclusive use of the invention in a cascade that ends with a full patent term is distinguishable from extending it by a *set* duration. *Cf. McClurg v. Kingsland*, 42 U.S. 202, 206 (1843) (sustaining a limited extension of existing patent terms); *Eldred v.*

Ashcroft, 537 U.S. 186, 209-10 (2003) (existing copyright terms extended 20 years by Congress remained "limited," not "perpetual"). Helsinn's construction thus raises a substantial constitutional question.

"It is a time-honored doctrine that statutes and regulations are first examined by a reviewing court to see if constitutional questions can be avoided." *Wyman v. James*, 400 U.S. 309, 345 n.7 (1971) (citing *Ashwander v. TVA*, 297 U.S. 288, 345-48 (1936) (Brandeis, J., concurring)). *Crowell v. Benson*, 285 U.S. 22, 62 (1932) ("When the validity of an act of the Congress is drawn in question, and even if a serious doubt of constitutionality is raised, it is a cardinal principle that this Court will first ascertain whether a construction of the statute is fairly possible by which the question may be avoided."). The premise of constitutional avoidance is that "Congress did not intend" any meaning of a statute "which raises serious constitutional doubts." *Clark v. Martinez*, 543 U.S. 371, 381 (2005). While the courts must grant the AIA the full measure of deference owed to federal statutes, if a construction of post-AIA § 102(a)(1) appears unconstitutional, this Court has explained that "every reasonable construction must be resorted to, in order to save a statute from unconstitutionality." *Hooper v. California*, 155 U. S. 648, 657 (1895); Courts need not determine that the statute as construed by Helsinn would be unconstitutional; they are merely "obligated to adopt a saving construction ... ." *SKF USA, Inc. v. U.S. Customs & Border Prot.*, 556 F.3d 1337, 1349-50 (Fed. Cir. 2009) ("While we need not go so far to

sustain the statute here, ... the doctrine of constitutional avoidance is not 'irrelevant'.")

III. CONGRESS NEITHER CONSIDERED NOR INTENDED THE COLLATERAL ABANDONMENT OF THE "EXPERIMENTAL USE" DOCTRINE THAT IS INEXTRICABLY LINKED TO THE SETTLED MEANING OF "ON SALE" AND "PUBLIC USE."

Congress never enunciated in the legislative history of the AIA the construction of § 102(a)(1) of "otherwise available to the public" as Helsinn now advocates. Such a construction would eviscerate the carve-out in the nearly two centuries-old settled safe harbor of the "experimental use" doctrine discussed in I above.

Under the "experimental use" exception, "an inventor who seeks to perfect his discovery may conduct extensive testing without losing his right to obtain a patent for his invention — even if such testing occurs in the public eye." *Pfaff*, 525 U.S. at 64; *City of Elizabeth*, 97 U.S. at 133-34; *Kendall*, 62 U.S. at 328-9 (The inventor's obligations for securing a patent "by no means forbid a delay requisite for completing an invention, or for a test of its value or success by a series of sufficient and practical experiments... [which] may be highly advantageous, as tending to the perfecting the invention"); *Pennock*, 27 U.S. at 18-19 (Story, J.) ("The use, as well as the knowledge of his invention, must be indispensable to enable him to ascertain its competency to the end proposed, as well as to perfect

its component parts. The words ['not known or used before the application'] then, to have any rational interpretation, must mean, not known or used by others, before the application.") Proof of experimental use before the invention is ready for patenting serves "as a negation of the statutory bars." ***EZ Dock v. Schafer Sys., Inc.***, 276 F.3d 1347, 1352 (Fed. Cir. 2002). A use may be experimental if its purpose is: "(1) [to] test claimed features of the invention or (2) to determine whether an invention will work for its intended purpose — itself a requirement of patentability." ***Clock Spring, L.P. v. Wrapmaster, Inc.***, 560 F.3d 1317, 1327 (Fed. Cir. 2009). The purpose of this doctrine is to discourage "paper inventions," sketchy disclosures and incomplete patent applications. It encourages experimentation, field testing under service conditions, and efforts to perfect an invention.

In ***Polara Engineering Inc v. Campbell Co.***, 894 F.3d 1339 (Fed. Cir. 2018), the Federal Circuit described the relevant factors that courts should consider to assess the existence of a bona fide experimental use. These factors include "(1) the necessity for the public testing, (2) the amount of control over the experiment retained by the inventor, (3) the nature of the invention, (4) the length of the test period, (5) whether any payment was made, (6) whether there was a secrecy obligation, (7) whether records of the experiment were kept, (8) who conducted the experiment, (9) the degree of commercial exploitation during testing, (10) whether the invention reasonably requires evaluation under actual conditions of use, (11) whether testing was systematically performed, (12) whether the inventor

continually monitored the invention during testing, and (13) the nature of contacts made with potential customers." *Id.* at 1348 (citing *Clock Spring,* 560 F.3d at 1327).

However, under Helsinn's theory that the AIA *substantively* modified the terms "on sale" and "public use" to bar patentability due to any activity that makes the invention "otherwise available to the public," the inquiry under the Federal Circuit's 13 factors listed above would be abrogated as irrelevant because of this catch-all *literal* statutory bar to patentability. In other words, it would be wholly illogical to assume that absent any statutory guidance, the AIA's "otherwise available to the public" clause arbitrarily altered the "on sale" bar only in the manner that Helsinn favors, but not in the manner that also repeals the experimental use doctrine. Indeed, Helsinn is silent on the experimental use doctrine, let alone explaining why courts should continue to consider *Clock Spring's* Factor 9 – "the degree of commercial exploitation during testing" – but totally ignore such factor during an indefinite secret commercialization, as would be required under the repeal of *Metallizing*.

Accordingly, the interpretation urged by Helsinn, should this Court adopt it, would repeal the experimental use exception and would lead to frequent loss of patent rights. It would fundamentally disrupt research, development, management and many established engineering procedures in industries. It would also undermine optimizing inventions for maximum public safety.

For example, in *Polara Engineering*, the invention of accessible pedestrian signal systems and pedestrian push buttons related to public safety in crossing the street. The inventors "needed to ensure the invention's durability and safety before being certain that it would work for its intended purpose." *Polara*, 894 F.3d, at 1350. "[D]urability and safety of the system could not be ascertained without it being subjected to use for a considerable period of time under different actual use conditions, *e.g.*, different crosswalk sizes and configurations and different environments. Experimenting under actual use conditions necessitated that the testing occur at public intersections." *Id.* at 1350. Under Helsinn's interpretation of the statute, inventions such as Polara's would not be perfected, nor patented, because the necessary experimentation would make the invention "available to the public."

In the biomedical technologies requiring FDA approval, the sheer number of people involved and the public nature of the testing in large-scale trials to generate the necessary clinical data required by the FDA is similarly likely to make the invention "available to the public." In addition, medical device manufacturers may need to charge the investigators performing the clinical testing or the patients for the new medical device in order to defray costs. While under some criteria the invention would be later (in hindsight) considered to have been ready for patenting before trials began, until clinical testing on humans, it may not be known whether the inventive device or treatment produce unwanted side effects even though it might work for the intended purpose. Additional iteration of the invention might

be required before the filing of an application that adequately "describe[s] the manner and process of making and using the invention so as to enable a person of skill in the art to make and use the full scope of the invention *without undue experimentation*." *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1344–45 (Fed. Cir. 2005) (emphasis added). Thus, under Helsinn's construction, such public experimentation may not be possible without the loss of patent rights.

Apparently, none of these impediments to entire industries were discussed during the AIA's legislative process. Congress gave no consideration to applicants' reliance on "experimental use" for perfecting and vetting inventions prior to filing complex patent applications. These issues are but the tip of an iceberg. Congress could not have intended to undermine entire industries and their innovation business conduct by foreclosing on the "experimental use" through stealth parsing of sentence text and grammatical punctuation exercises. *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001) ("Congress ... does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes."); *Kellogg Brown & Root Servs., Inc. v. U.S., ex rel. Carter*, 135 S. Ct. 1970, 1977 (2015) ("Fundamental changes in the scope of a statute are not typically accomplished with so subtle a move.")

IV. CONGRESS DID NOT INTEND TO REPEAL THE PATENT FORFEITURE BARS

Throughout Congress' patent policy trajectory over the years one sees consistent efforts to maintain, if not strengthen, the forfeiture bars against pre-grant delays after invention; taken as a whole, Congress did not disturb the established meaning of the terms "on sale" and "public use."

IV.A Helsinn's purported repeal permits an *indefinite* grace period for secret exploitation of inventions for which Congress evidenced no intention

Helsinn's theory that the AIA repealed the patent forfeiture bars for secret commercialization and non-informing public use would permit inventors to secretly practice an invention indefinitely prior to filing an application, effectively making the pre-AIA's one-year grace period for such activities *indefinite* under post-AIA law. If that were truly a goal of the AIA, which it is not, it would prove a radical departure from Congress' clear historical policy record since the mid-19th century. Congress' policy record has been that of *shortening*—not extending—the exclusive period from invention to patent expiration. This is shown in statutes that shortened the permitted period between invention and filing, between filing and patent issuance, or the period over which the patent is in force. The following list is illustrative:

(a) In the Act of March 2, 1861, Ch. 88, § 16, 12 Stat. 249 (1861), Congress repealed patentees' ability to extend their patent term up to 21 years after grant and set the patent term at 17 years from grant.

(b) In the Act of March 3, 1863, Ch. 102, §3, 12 Stat, 796 (1863), Congress shortened the period to pay the patent issue fee to 6 months after allowance, or the application considered abandoned, eliminating applicant practice of delaying the patent issuance.

(c) In the Act of March 3, 1897, Ch. 391, § 4, 29 Stat, 693 (1897), Congress shortened the time to complete an application for examination from 2 years to 1 year after initial filing, and shortened the time to respond to all Office actions from 2 years to 1 year. Failing to meet these deadlines results in forfeiture (abandonment) of the application.

(d) In the Act of May 23, 1908, PL 60-133, Ch. 189, 35 Stat, 246 (1908), Congress provided that patents shall issue 3 months from payment of issue fees, eliminating patent issuance delays by the Patent Office.

(e) In the Act of June 25, 1910, PL 61-296, Ch. 414, 36 Stat, 843 (1910), Congress repealed R.S. § 4902, the statute that allowed inventors to file caveat patent disclosure in the patent office, as means of deferring for up to one year their filing an application, during which time the Patent Office would notify the caveat holder

of any similar applications on the same subject matter if and when filed.

(f) In the Act of March 2, 1927, PL 69-690, Ch. 273, 44 Stat, 1335 (1927), Congress shortened the time to complete an application for examination from 1 year to 6 months after filing, and shortened the time to respond to all Office actions from 1 year to 6 months. Failing to meet these deadlines results in abandonment of the application.

(g) In the Act of August 5, 1939, PL 76-286, Ch. 450, 53 Stat, 1212 (1939), Congress *reduced the grace period* for inventors' disclosures, publications, "on-sale," and "public use" activities from two years to one year before filing an application. "Under present conditions 2 years appears unduly long and operates as a handicap to industry. Reduction of the period would serve *to bring the date of patenting closer to the time when the invention is made*, and would expedite applications, not only in their filing but also in their progress through the Patent Office." S. Rep. 876, 76 Cong. 1st Sess. (July 18, 1939) at 1. (Emphasis added).

(h) In the Act of August 7, 1939, PL 76-341, Ch. 568, 53 Stat, 1254 (1939), Congress provided the Commissioner with authority to set shorter times for reply to an office action not to be less than 30 days and not to exceed 6 months. This flexibility reduces pendency—the total time from filing to patent issuance.

(i) In the Act of August 9, 1939, PL 76-358, Ch. 619, 53 Stat, 1293 (1939), Congress repealed R.S. § 4897, which, as a matter of right, provided for revival of an application for which the issue fee was not timely paid, referring instead the decision to revive to the discretion of the Patent Commissioner. The previous statute "readily permits the deliberate postponement of the issuance of a patent and is resorted to mainly for this purpose. [ ] The proposed change eliminates renewals, consequently simplifying the practice and abolishing causes and opportunities for delays." S. Rep. 878, 76 Cong. 1st Sess. (July 19, 1939) at 1-2.

(j) In the Patent Fee Act of July 24, 1965, PL 89-83, 79 Stat. 259 (1965), Congress provided that patent issue fee be paid earlier after allowance, with ability for later corrective payment to cover the (initially unknown) printed page count fee component. "This particular arrangement will permit the Patent Office to *issue patents substantially sooner* and make new technology available to the public at an *earlier date*." S. Rep. 301, 89th Cong. 1st Sess. (June 8, 1965) at 5. (Emphasis added).

(k) In the Patent Office Appropriations Act of August 27, 1982, PL 97-247, 96 Stat, 317 (1982), Congress amended 35 U.S.C. § 41 to provide graduated discounted extension-of-time fees to incentivize applicants to reply *sooner* than 6-months to an Office action; it also established escalating maintenance fees to

incentivize *early expiration* of unexploited patents. Both factors have the effect of shortening the exclusive period ending on patent expiration.

(l) In the Uruguay Round Agreements Act of December 8, 1994, PL 103-465, 108 Stat 4809, (1994), Congress changed the term of a patent from 17 years after grant to 20 years counted from the original application date. For substantial number of applications, this had the effect of shortening the exclusive period from invention to patent expiration.

To be sure, Congress also enacted statutes that extend the patent term, but that was to compensate patentees on a day-per-day basis for erosion of their patent term due to unusual government agency delay. *Drug Price Competition and Patent Term Restoration Act of 1984*, PL 98-417, 98 Stat. 1585 (Sept. 24, 1984); *Patent Term Guarantee Act of 1999*, PL 106-113, 113 Stat. 1501A-557 (Nov. 29, 1999).

A repeal of the inventors' forfeiture bars would be an extraordinary departure from Congress' persistence for two centuries in curtailing delays in invention disclosure and patenting. This persistence is unmistakable even leading up to the AIA through previous iterations of patent reform bills that included first-to-file provisions. In adopting and reporting H.R. 1908, a precursor bill to the AIA passed by the House, the House Judiciary Committee Report explained that it "uses the current § 102(b) as the template from which to define the scope of prior art in the Act, primarily

because of how the terms 'in public use' and 'on sale' have been interpreted by the courts." H. Rep. 110–314, 110th Cong. 1st Sess. (Sep. 4, 2007), at 57. The report further explained that the bill's provisions "are meant to ... encourag[e] inventors *to file early* for patent protection, [and] *prevent*[ ] *inventors from extending their monopoly* in the invention." *Id.* (Emphasis added). Notably, the report explains that "there is nothing inherent in a first-to-file system that will deter inventors from making use of their inventions as trade secrets and then some time later filing a patent application for the invention. *Thus, the maintenance* of the "public use" and "on sale" definitions of prior art *are needed to prevent such activity*." *Id.* (Emphasis added).

No proposed congressional policy contradicting this "need to prevent such activity" was subsequently published prior to the enactment of the AIA.

IV.B Congress has not considered the real effects of repealing the secret commercialization patent forfeiture bars

When members and committees of Congress were presented with amendments to the statutory language that would have repealed the patent forfeiture bars for secret commercialization and non-informing public use, they rejected it. See Resp. Br. at 9-12. Indeed, "Congress reject[ed] ... the very language that would have achieved the result [that Helsinn] urges here," which "weighs heavily against [Helsinn's] interpretation." *Hamdan v. Rumsfeld*, 548 U.S. 557, 579-80 (2006). For an industry sector to have pursued such repeal, it would have been

important to explain to members of Congress why the public interest would be better served by permitting an inventor to delay filing of a patent application of an invention that is ready for patenting after commercially exploiting it in secret.

For example, it would have been necessary for chemical companies or pharmaceutical companies to explain that the public interest would be better served if after taking out a patent on a *composition* of a compound or a drug, they would be permitted to keep the *process of making* the compound or the drug a trade secret, and still be allowed years later to file and obtain a patent on that *process*. In some circumstances, this policy would allow daisy-chaining and extending patent protection beyond an intended legislated term. There is no evidence that a case was ever made to Congress for such policy prior to the enactment of the AIA.

Instead, the dominant policy matters discussed in Congress in the years leading up to the AIA with respect to amending § 102 were matters regarding the First-to-File vs. the First-to-Invent systems, interferences, the virtual elimination of the grace period, and *other* effects of the redefinition of prior art. The prospect of allowing—even incentivizing—inventors to delay for years filing patent applications is inconsistent with a stated goal of prompt filing of patent applications. S. Rep. 110-259, 110th Cong. 2nd Sess. (Jan. 24, 2008) at 7 ("[A] first to file system encourages the *prompt* filing of patent applications.") (Emphasis added); H. Rep. 110–314, 110th Cong. 1st Sess. (Sep. 4, 2007) at 57 ("The [first-to-file] provisions ... are meant to serve a set of very specific

policy goals [including] encouraging inventors to *file early* for patent protection"). (Emphasis added).

Indeed, the proposals made in policy studies recommending patent reforms and the AIA's legislative history during 2005-2011, including congressional bills and committee hearings, were analyzed in detail. The analysis reveals that neither the notion nor the implications of repealing the "on sale" and "public use" forfeiture bars were ever brought up before Congress. *See* Daniel Taskalos, "Metallizing Engineering's Forfeiture Doctrine After the America Invents Act, 16 *Stan. Tech. L. Rev.* 657, 680-700 (2013).

IV.C Congress could not have intended to effectuate the policies underlying the repeal of the forfeiture bars

Were the Court to adopt Helsinn's construction of the statute, it would enable companies to extend their commercial exclusivity indefinitely by hoarding, exploiting, and profiting secretly from certain technologies for years and then taking out patents on these technologies. It would also permit market incumbent companies to "evergreen" their old secret technologies into a windfall of patents on subject matter for which patent protection had long been forfeited under pre-AIA law. This windfall will disproportionately enrich older and established market incumbents to the detriment of early-stage startups that are too young to have accumulated older secret technology.

Judge Markey remarked: "[O]ur Forefathers had some experience with that from the Guilds in Europe

and did not want a secret technology. They created the patent system to encourage disclosures." Howard T. Markey, "Some Patent Problems," 80 *F.R.D.* 203, 206 (1978) (discussing the patent bargain).

If inventors are afforded unlimited or unspecified exclusive period to commercially exploit their inventions in secret, they would have less incentives to disclose their invention early. *Pennock*, 27 U.S. at 19; Katznelson, *supra*, at 89; Crawley, *supra*, at 24. Consequently, substantial duplication of R&D may ensue; and those participating in the patent system—those patent seekers who disclose early—would be subject to greater risks. First, there would be an asymmetric flow of information to the hoarder of secrets—the only beneficiary from this information exchange. Second, because those seeking patents must disclose their technology and its progression, the hoarder of secrets can ambush the patent-seeker by tracking their progress and preemptively filing a patent application whenever it appears that the patent seeker is close to discovering the undisclosed subject matter possessed by the hoarder of secrets. That would tip the balance of risks against those who participate in the patent system. This is akin to card players in a rigged game wherein one player is subject to a rule requiring him to reveal his hand to his opponent who is not subject to that same disclosure rule and thus keeps his hand secret. This shift of risks from those who hoard secrets to those who participate in the patent system is nothing short of a recipe for undermining the American patent system.

IV.D Congress has not abandoned the equitable common-law rules that continue to operate alongside the statutory terms

The pre-AIA patent-defeating statutory language invoking the terms "on sale" and "public use" does not expressly distinguish between pre-filing use of the invention by the inventor over that of others. Yet, courts have acknowledged that a construction that makes such distinction is necessary on *equitable grounds* to serve the same policy goals embodied in the statutory bars. *Pennock*, 27 U.S. at 18-19 (Story, J.); *Pfaff*, 525 U.S. at 64; *City of Elizabeth*, 97 U.S. at 133-34; *Kendall*, 62 U.S. at 328-9 ; *D.L. Auld*, 714 F.2d at 1148; *Metallizing*, 153 F.2d at 520. Such distinction leading to the equitable forfeiture bar and the experimental use exception is inherently under the *inventor's* control, not the public, over conduct that leads to sales and public use of his invention; this distinction is necessary when applying the principles of equity to curtail inventor's opportunism in extending the effective exclusive period. *Id.* at 520 (by "making use of his secret to gain a competitive advantage over others," the inventor would "thereby extend the period of his monopoly").

Because the relevant circumstances and dispositive evidence in such pre-patenting activities are case-specific and span a wide spectrum of relevant factors, the breadth and flexibility of equitable doctrines must apply alongside the statute for "avoiding mechanical rules." *Holland v. Florida*, 560 U.S. 631, 650 (2010) (citing, e.g., *Hazel-Atlas Glass*

Co. v. Hartford-Empire Co., 322 U.S. 238, 248 (1944) (doctrines of equity are used to "relieve hardships which, from time to time, arise from a hard and fast adherence" to absolute legal rules, which, if strictly applied, threaten the "evils of archaic rigidity"); *Swann v. Charlotte-Mecklenburg Bd. of Educ.*, 402 U.S. 1, 15 (1971) (declaring that "breadth and flexibility are inherent in equitable remedies").

The need for avoiding the "evils of archaic rigidity" by employing equitable factors is not unique to the proper interpretation of the statutory patenting bars. Indeed, analysis of this Court's jurisprudence over the last several decades illustrates this Court's general equity-protective presumption in interpreting federal statutes. *See* Leigh T. Anenson, "Statutory Interpretation, Judicial Discretion, and Equitable Defenses," 79 *U. Pitt. L. Rev.* 1, 21-24 (2017). In fact, because of the need for "avoiding mechanical rules," this approach for ascertaining statutory meaning is an instrument on which Congress relies. *Astoria Fed. Sav. & Loan Assn. v. Solimino*, 501 U.S. 104, 108 (1991) ("Congress is understood to legislate against a background of common-law adjudicatory principles" and to incorporate them "except when a statutory purpose to the contrary is evident" (internal quotation marks and citation omitted)). "In order to abrogate a common-law principle, the statute must 'speak directly' to the question addressed by the common law." *United States v. Texas*, 507 U.S. 529, 534 (1993) (citation omitted); *Beck v. Prupos*, 529 U.S. 494, 500 (2000) ("[W]hen Congress uses language with a settled meaning at common law, Congress presumably knows and adopts the cluster of ideas

that were attached to each borrowed word in the body of learning from which it was taken and the meaning its use will convey to the judicial mind unless otherwise instructed. In such case, absence of contrary direction may be taken as satisfaction with widely accepted definitions, not as a departure from them.") (quoting *Morissette v. United States*, 342 U.S. 246, 263 (1952), quotation marks omitted).

This was Congress' statutory approach in Section 102(b) of the Patent Act of 1952, incorporating the equitable doctrines surrounding the forfeiture bars and experimental use exceptions thereto long after they were well-developed judicially, and subsequently its approach in retaining the common law and these equitable doctrines by preserving the terms "on sale" and "public use" in the AIA.

Helsinn acknowledges that the post-AIA statute "can encompass items 'not specifically enumerated' in a statute." Pet. Br. at 36. Helsinn's theory, however, is that by inserting the AIA's modifier "otherwise available to the public," Congress jettisoned the equity-protective presumption in interpreting the statutory terms "on sale" and "public use" as being unnecessary — that the statutory change and the first to file system leave no room for the pre-AIA equitable factors. Hence, Helsinn counterfactually posits:

> "[the shift to the first to file system] fundamentally altered the justification for the on-sale bar. Before the AIA, when patentability hinged on who was first to invent, an inventor could effectively extend the available patent

> term by selling the invention in secret. Under the AIA, however, an inventor who does not immediately file for a patent takes the risk that another inventor will file the first patent application and thus have priority. As a result, it is unnecessary for the on-sale bar to provide inventors with an additional incentive to enter the patent system promptly."

Pet. Br. at 16. This is a non-sequitur because the AIA's first to file rule does *not* change the fact that under Helsinn's construction, the inventor can still "effectively extend the available patent term by selling the invention in secret." Under this construction, filing delay is actually incentivized, not merely for the one-year pre-AIA grace period, but for an *unbounded* period.

That the first to file provision alone does not materially change the policy animating the equitable forfeiture bars is clear from the House explanation for maintaining the "on sale" and "public use" terms in the AIA's predecessor H.R. 1908, which included the first to file provision: "there is nothing inherent in a first-to-file system that will deter inventors from making use of their inventions as trade secrets and then some time later filing a patent application for the invention. *Thus, the maintenance* of the "public use" and "on sale" definitions of prior art *are needed to prevent such activity*." H. Rep. 110–314, 110th Cong. 1st Sess. (Sep. 4, 2007) at 57 (emphasis added). In fact, by expanding the prior user rights in 35 U.S.C. § 273, the AIA *further reduces* the risk for those engaged in such delay activity. These affirmative defense rights protect the commercial

user from patent infringement claims asserted by another inventor of the same subject matter if the commercial use commenced at least 1 year before the filing of the asserted patent's application.

In *City of Elizabeth*, this Court held that testing an inventive pavement for "usefulness and durability" for six years on a public roadway constituted experimental use. 97 U.S. 126, 133-34. It applied the "experimental use" doctrine as an equitable exception to the patent forfeiture bar. This is part of the common law. There is no indication that in enacting the AIA, Congress intended to abandon the equitable rules that operate alongside the statutory patenting bar – "a statutory purpose to the contrary" is *not* evident. *Astoria*, 501 U.S. at 108. There is no evidence that Congress changed the balance of the equities or substituted any of the equitable factors so as to change the meaning of the terms "on sale" or "public use." Because the post-AIA statute uses the same terms and does not "speak directly to the question addressed by the common law," the old common law continues to apply.

CONCLUSION

For the foregoing reasons, the holding of the Federal Circuit below should be affirmed and this Court should clarify that the statutory meaning of the terms "on sale" and "public use" have not changed by the enactment of the AIA.

Respectfully submitted,

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